REMARKS

The indication of allowable subject matter in claims 2-4, 8-12 and 14-28, as is the Examiner's clear and detailed Office Actions, is acknowledged and appreciated. For the following reasons, it is respectfully submitted that all claims are in condition for allowance.

Claims 1, 5, 6 and 7 stand rejected under 35 U.S.C. § 103 as being unpatentable over Corey ('589). This rejection is respectfully traversed for the following reasons.

According to one exemplary embodiment of the present invention, a sample can need to be opacified to generate the standard curves, whereas in contrast the turbidity of a sample in Corey whose concentration has been determined is measured *after* a reagent is mixed therein. Corey is silent as to a measurement before mixing the reagent into the sample.

One of the objects of the present invention is to allow determination of the quantity of a sample whose concentration is unknown. In addition, by measuring the turbidity before mixing as can be done in the present invention, it is also possible to determine the quantity of an *inherently* turbid sample. Corey is silent as to the possibility of an inherently turbid sample, let alone suggest a process by which the quantity of the sample can be accurately determined. Accordingly, the present invention can provide advantages over the prior art.

Claim 1 recites in pertinent part, "measuring intensities ... before and after mixing therein" a reagent. The Examiner admits that this step is not disclosed by Corey, but alleges that such a process would have been obvious "to generate the spectrophotometric standard curve used to calibrate protein amount."

A. generating standard curve not equivalent to measuring protein concentration

As a preliminary matter, it is respectfully submitted that the steps involved in generating standard curves are not part of the process for "measuring a concentration of protein" as embodied by claim 1. That is, generating standard curves is based on samples whose protein concentrations are already known so as to generate curves which show the relationship between the ***known*** protein concentrations and detected light intensity. The process of generating standard curves is separate and distinct from a process for measuring protein concentration of a test sample having an ***unknown*** protein concentration. Accordingly, it is submitted that the Examiner's reliance on the alleged teachings related to the process of generating standard curves is not applicable to the process of measuring a concentration of protein recited in claim 1.

As such, even assuming *arguendo* that "it is well appreciated in the art that a 'zeroing' sample be used to calibrate the spectrophotometer" during a calibration process using known protein concentrations as alleged by the Examiner, such a conclusion nonetheless does not disclose or suggest that a "zeroing" sample is used during a process which can measure an unknown concentration of protein as embodied by claim 1.

B. Applicant discovered source of problem rendering alleged obviousness of remedy moot

Nevertheless, it is respectfully submitted that the Examiner's allegation that "given conventional laboratory techniques, absorbance is measured in samples before the addition of reagents in order to generate a baseline for the measurements" is based solely on improper hindsight reasoning using only Applicant's specification as a guide to reconstruct the claimed invention. The cited prior art is completely silent as to the need for baselining measurements, let alone specifically for protein concentration. Moreover,

even assuming *arguendo* baselining measurements is known ***generally***, it is respectfully submitted that baselining measurements for protein concentrations in particular is not known.

As described for example on page 23, line 1- page 24, line 8 of Applicant's specification, only Applicant has discovered the problems associated with inherent turbidity of a sample (e.g., urine) and the means by which to more accurately measure actual protein concentration by eliminating the influence of inherent turbidity. The cited prior art does not recognize nor consider such problems, nor suggest possible solutions. Indeed, the cited prior art overlooks the possibility of inherent turbidity in samples and is therefore subject to flawed measurements (which may be acceptable for prior art purposes) for protein concentration when samples have inherent turbidity.

The Examiner is directed to MPEP 2141.02 under the heading entitled "Discovering Source/Cause of a Problem is Part of 'As a Whole" Inquiry", which sets forth the applicable standard:

> A patentable invention may lie in the discovery of the source of a problem even though the remedy may be obvious once the source of the problem is identified. (citing *In re Sponnoble*, 160 USPQ 237, 243 (CCPA 1969)).

In the instant case, it is respectfully submitted that the Examiner's obviousness allegations are directed only to the "remedy" as described in the above-cited MPEP section. Accordingly, even assuming *arguendo* the general "remedy" of baselining is obvious as alleged by the Examiner, none of the cited prior art identifies the source of problems specifically in protein measurement processes let alone suggest the need for such baselining in protein measurements. Indeed, as described for example on the last four lines of page 22 of Applicant's specification, only Applicant has discovered one of the

"sources" of inherent turbidity in measuring protein concentration of samples such as urine, resulting from precipitation of various kinds of salts. In contrast, the cited prior art presumes that samples before mixing of the reagent are transparent so that a measurement before mixing the reagent is not necessary. The cited prior art therefore does not consider nor contemplate the possibility of inherent turbidity let alone the potential skewing of the protein concentration measurements resulting therefrom.

C. measuring light intensity before mixing reagent for protein measurements not disclosed or suggested by prior art

Furthermore, as set forth in MPEP § 2143.03 under the section entitled "All Claim Limitations Must Be Taught or Suggested", to establish *prima facie* obviousness of a claimed invention, ***all*** the claim limitations must be taught or suggested ***by the prior art*** (see *In re Royka*, 180 USPQ 580 (CCPA 1974). In the instant case, the pending rejection does not "establish *prima facie* obviousness of [the] claimed invention" as recited in claim 1 because Corey fails the "all the claim limitations" standard required under § 103.

That is, none of the cited prior art discloses taking measurements ***before*** the reagent is mixed into the sample, let alone suggests a need or desire for doing so. It appears the Examiner is relying on Official Notice that taking measurements before the reagent is mixed into the sample and a need or desire for doing so in a protein measurement process is known. However, for the reasons discussed above and pursuant to MPEP § 2144.03(C), Applicant hereby challenges the Examiner's allegations that taking protein concentration measurements before the reagent is mixed into the sample is known and modifying Corey to do so would be obvious, and respectfully requests documentary evidence of her findings if the pending rejection is maintained.

D. no motivation for modifying Corey

Moreover, even assuming *arguendo* that the Examiner finds prior art disclosing baselining generally whereby all aspects of the claimed invention could be individually known in the art, it is submitted that such a conclusion is not sufficient to establish a *prima facie* case of obviousness because there is no ***objective*** reason on the record to combine the teachings of the cited prior art. The Examiner is further directed to MPEP § 2143.01 under the subsection entitled "Fact that the Claimed Invention is Within the Capabilities of One of Ordinary Skill in the Art is Not Sufficient by Itself to Establish *Prima Facie* Obviousness", which sets forth the applicable standard:

> A statement that modifications of the prior art to meet the claimed invention would have been [obvious] because the references relied upon teach that all aspects of the claimed invention were ***individually*** known in the art is ***not*** sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references. (citing *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993)).

In the instant case, as mentioned above, none of the cited prior art recognized or considered the problems associated with inherent turbidity in protein measurement processes so that measuring before the reagent is mixed would not be necessary, leaving a proposed modification of Corey without the requisite objective evidence from the prior art.

A *prima facie* showing of obviousness can only be established if the prior art "suggests the desirability" of the proposed modification using objective evidence. The Examiner is directed to MPEP § 2143.01 under the subsection entitled "Fact that References Can Be Combined or Modified is Not Sufficient to Establish *Prima Facie* Obviousness", which sets forth the applicable standard:

> The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. (*In re Mills*, 16 USPQ2d 1430 (Fed. Cir. 1990)).

In the instant case, even assuming *arguendo* that Corey can be modified to reach the claimed invention, it is submitted that the "mere fact that [Corey] can be modified ... does not render the resultant modification obvious" because nowhere does the ***prior art*** "suggest the desirability of the modification" as set forth by the Examiner. As mentioned above, the cited prior art is silent as to the existence of inherent turbidity specifically for protein measurements, let alone its effect on measurement accuracy and the means by which to reduce such effects (e.g., measuring before reagent mixed therein). In sum, the cited prior art is silent as to "suggesting the desirability" of measuring light intensities ***before*** mixing a reagent into the sample.

Under Federal Circuit guidelines, a dependent claim is nonobvious if the independent claim upon which it depends is allowable because all the limitations of the independent claim are contained in the dependent claims, *Hartness International Inc. v. Simplimatic Engineering Co.,* 819F.2d at 1100, 1108 (Fed. Cir. 1987). Accordingly, as claim 1 is patentable for the reasons set forth above, it is respectfully submitted that dependent claims 5, 6 and 7 which depend on claim 1 are also patentable. In addition, it is submitted that claims 5, 6 and 7 are patentable based on their own merits by adding novel and non-obvious features to the combination.

For example, it is respectfully submitted that Corey does NOT disclose or suggest the feature of claim 5. Claim 5 recites in pertinent part, "wherein the protein concentration in said solution to be detected is determined based on the intensities of said transmitted light ***and*** said scattered light" (emphasis added). The Examiner relies on Corey to reject

claim 5, but does not identify how Corey discloses the feature recited therein. Indeed, Corey appears silent as to the type of light being measured (i.e., transmitted or scattered), let alone disclose using ***both*** transmitted light and scattered light. As described on, for example, page 16, lines 4-14 of Applicant's specification, measuring both types of light intensities can eliminate conventionally needed steps such as diluting solutions in the high concentration range, thereby increasing accuracy and efficiency, etc..

Based on all the foregoing, it is submitted that claims 1, 5, 6 and 7 are patentable over Corey. Accordingly, it is respectfully requested that the rejection of claims 1, 5, 6 and 7 17 under 35 U.S.C. § 103 over Corey be withdrawn.

CONCLUSION

Having fully and completely responded to the Office Action, Applicant submits that all of the claims are now in condition for allowance, an indication of which is respectfully solicited. If there are any outstanding issues that might be resolved by an interview or an Examiner's amendment, the Examiner is requested to call Applicant's attorney at the telephone number shown below. To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 500417 and please credit any excess fees to such deposit account.

Respectfully submitted,
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